Whistleblower charges drug company with deceptive practices

Jeanne Lenzer *New York*

A former drug company insider has spoken to reporters for the first time since he filed a whistleblower lawsuit in 1996 in a US federal court.

At a press conference last week he gave details of the suit he has filed.

The suit charges that Parke-Davis engaged in elaborate inducement schemes to persuade doctors to promote the off-label use of one of its best selling drugs, gabapentin (Neurontin), an anti-epileptic drug approved as adjunctive treatment for partial seizures. It also says the company ran ghost writing schemes, in which it paid specialists to "author" articles that were actually written by technical writers hired by the company.

Prescribing drugs off label accounts for over 78% of sales of gabapentin, according to Parke-Davis. Although off-label prescribing is legal, the US Food and Drug Administration prohibits drug companies from promoting such use to doctors. Parke-Davis, which was a division of Warner-Lambert when the promotional activities are alleged to have occurred, was acquired by Pfizer in 2000.

Dr David Franklin, a microbiologist and former fellow of Harvard Medical School, sought legal assistance from the Boston law firm Greene and Hoffman when he became concerned about patients' safety and that his employers might retaliate against him because of questions he had been raising about apparent illegal marketing practices.

Dr Franklin, 41, said he had been working as a "medical liaison" employee for Parke-Davis for only four months when a company executive warned that he "couldn't guarantee what is going to happen to you or your career" if Dr Franklin continued to challenge the marketing scheme.

Dr Franklin says Parke-Davis executives were worried about its market for gabapentin, as its original patent was set to expire in December 1998—and because it was approved for use only as adjunctive treatment in patients with partial seizures.

In an amended complaint filed in July 2001 Dr Franklin alleges: "After performing extensive economic analysis, senior officials at Parke-Davis determined that it was not sufficiently profitable for Parke-Davis to obtain FDA approval for Neurontin's alternative uses."

Although federal regulations would not allow Parke-Davis to promote gabapentin for unapproved uses, drug companies are allowed to distribute third party publications promoting off-label use in response to unsolicited requests.

Dr Franklin charges that the company undertook an elaborate programme to exploit this "narrow window of opportunity." He said "tens of thousands of payments" to doctors were made for "consultations" and "studies" and served as a "surrogate sales force," violating Medicaid regulations on kickbacks.

According to Dr Franklin, "Significant ingenuity and resourcefulness was necessary in order to execute this unlawful scheme without detection."

A thinly disguised incentive scheme to get doctors to prescribe the drug off label was to pay them as "consultants" to attend lavish, all expenses paid trips to resorts where doctors were encouraged to prescribe the drug for disorders ranging from migraine to bipolar disorder to attention deficit disorder.

Even though the doctors were listed as consultants, Dr Franklin says their comments were not even recorded at some of the events. "Studies" supporting such uses of the drug, alleges Dr Franklin, ranged from occasional case reports falsely labelled as studies to non-existent data. In the case of bipolar disorder no study has actually shown that the drug has any benefit over placebo.

Dr Franklin also says that Parke-Davis paid specialists to "author" articles that were actually ghost written by non-physician technical writers hired by the company. The articles were then filtered through "medical education" companies, which in turn submitted the articles for publication. Court documents cite 20 articles produced in this manner.

Pfizer would not comment on any aspects of the various actions, saying only, "We acquired Warner-Lambert in June 2000, and the events date back to many, many years before that. Pfizer does not promote off-label use of drugs." □

US body reviews errors in emergency departments

Roger Dobson *Abergavenny*

About 2000 medication errors in hospital emergency departments are reported annually in the United States, a new report says.

The US Pharmacopeia, an independent non-governmental organisation that monitors drug safety, has now made a series of recommendations aimed at lowering the number of errors. The organisation had analysed data on medication errors held on its national databases, which contain more than 360 000 reports of such errors since 1998. In 2001, hospitals reported more than 2000 medication errors in emergency departments.

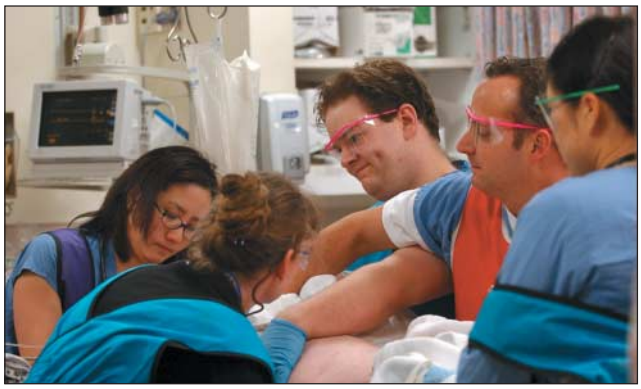
The data show that, compared with other hospital departments, fewer emergency department mistakes are picked up before they reach the patient. US Pharmacopeia found that in the emergency departments, 23% of errors were intercepted before reaching patients, compared with 39% in other areas.

The results show that, of the 105 603 errors documented by MEDMARX (the anonymous national database for reporting medication errors), 2063 (2%) of total errors were in the emergency department; although most of these were corrected before causing harm to the patient, 147 (7%) resulted in patients being harmed. Of those cases, 123 resulted in temporary harm to the patient and required intervention; 21 resulted in admission to hospital; one may have contributed to or resulted in permanent harm; another required lifesaving intervention; and one resulted in a patient's death.

US Pharmacopeia pinpoints the most frequent errors as prescribing errors, omission errors, failure to administer a prescribed medication, and dosage errors. The analysis shows that three quarters of medication errors in emergency departments occurred during prescribing and administering drugs.

"Patients seen in the emergency department tend to be those most in need of urgent care," said Diane Cousins, vice president of US Pharmacopeia's Center for the Advancement of Patient Safety. "Timing is often critical, and medications must be dispensed and administered quickly. In haste, however, medication errors can occur." □

Summary of Information Submitted to MEDMARX in the Year 2001: A Human Factors Approach to Medication Errors is available at www.usp.org/medmarx2001



ELAINE THOMPSON/AP

Emergency room workers treat a trauma patient in Seattle. A new report based on anonymous data says 2% of medication errors occur in emergency departments